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DRAFT AS OF 07-11-2003**

**CHAPTER 9
HARVESTER: SHELLSTOCK HARVESTING, HANDLING AND SANITATION**

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The section number for an existing regulation is noted in brackets [15.01] in the title section.

Title and notes section:

9.01 Compliance

(B) Note: See new permits for dealers to commingle product.

9.02 Shellstock Washing

9.03 Protection from Contamination

A. [16.17 (B)] and B. [16.12 (H)]

9.04 Shellfish Harvester Vessels

9.05 Vehicles Used to Transport Shellstock

9.06 [Chapter 48 and 15.08] Shellstock Tagging and Labeling

(G) Note: Scan example Harvester tag(s) at the end of this Chapter.

9.07 Shellfish Aquaculture

Note: 9.07 Provides compliance with the Model Ordinance Chapter VI

Note: Chapters 10.04(C) and 14.20 registrant sections should be repealed and/or updated for consistency with the Model Ordinance.

(B) Note: The biotoxins section in Chapter 2.90 will need to be updated for consistency with Chapter 9.07(B) and compliance with the Model Ordinance.

9.08 Shellstock Temperature Control

Note: Chapter 9.08 is from applicable Model Ordinance Chapter VIII Time Temperature Matrices.

Note: The Harvester's tag starts this process with the time of harvest on their tags. This is the mechanism to ensure that the harvesters and dealers are in compliance with the appropriate temperature matrix that the Department selects.

9.09 Recall Procedure

Notes: The recall procedure in 9.09 requires record keeping and the provision of the time of harvest on the harvester tags under 9.06(B)(4). This is Maine's alternative for compliance with the Model Ordinance that would otherwise require harvesters to sell only to certified dealers for fresh shellstock.

Non-compliance consequences, see 12 MRSA §6401, do not repeat in regulations.

(A) The 1-year retention is equivalent to the dealer's requirements.

(D) Add: No records necessary if sold only to certified dealers.

DISCUSSION DOCUMENT ONLY
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HARVESTER: SHELLSTOCK HARVESTING, HANDLING AND SANITATION

9.01 Compliance

- A. Closed Area compliance: Harvest of shellstock is prohibited in areas that are closed due to marine biotoxins pursuant to Chapter 96 and bacterial pollution pursuant to Chapter 95, and in those areas that may potentially be closed by the Department due to marine biotoxins or bacterial pollution. For details about closure lines contact Marine Patrol Division I, west of Port Clyde, Tel. (207) 633-9595 or Marine Patrol Division II, east of Port Clyde, Tel. (207) 667-3373, or telephone the Shellfish Sanitation Hotline at 1-800-232-4733 or on the web at: <http://www.maine.gov/dmr/shellfish%20sanitation%20hot%20line.htm>.
- B. Commingling of shellstock is prohibited, except that primary dealers, as defined in Chapter 15.02(68), who are authorized by the Department in accordance with Chapter 16.21(C), may commingle shellstock.
- C. Harvesters shall not conduct wet storage activities. Wet storage of shellstock is prohibited, except by certified dealers pursuant to a current permit issued by the Department under Chapter 15.32 – 15.35.

9.02 Shellstock Washing

- A. Shellstock shall be washed such as to be reasonably free of bottom sediments as soon after harvest as practicable.
- B. Shellstock shall be culled of dead, broken or gaping shellfish as soon after harvest as practicable.
- C. The harvester must wash the shellstock using one of the following methods:
 - 1. Wash the shellstock using water from a growing area classified as approved or conditionally approved in the open status at the time and place of harvest; or
 - 2. If shellstock washing is not feasible at the time of harvest, the certified dealer shall be responsible for washing using only water from an approved source.
- D. Shellstock shall not be placed in containers of stagnant water.
- E. Depuration harvesters may use growing area water in the restricted or conditionally restricted classification in the open status to wash shellstock at the time and place of harvest.

9.03 Protection from Contamination

- A. Shellstock shall be stored in a manner as to be protected from contamination.
- B. Containers used for storing shellstock shall be fabricated from safe materials, cleaned and maintained in a manner and frequency as necessary to protect shellstock from contamination.
- C. Shellstock transferred, shipped, handled or transported under conditions creating a potential for gross contamination, such as with boat motors, engine oil, antifreeze, dead animals, dirty tarps, bilge water, polluted overboard water, closed area water, stagnant water, etc., shall be subject to immediate embargo and/or destruction as being of unsound or unknown quality, and therefore, unsafe for human consumption.

DISCUSSION DOCUMENT ONLY
DOES NOT REPRESENT DEPARTMENT POLICY/REGULATION
DRAFT AS OF 07-11-2003

- D. Shellstock held or washed in closed area water shall be subject to immediate embargo and/or destruction as being of unsound or unknown quality, and therefore, unsafe for human consumption.
- E. Once landed, shellstock held or washed in water containing any other macro marine organism(s), such as lobsters, finfish, invertebrates, etc., shall be subject to immediate embargo and/or destruction as being of unsound or unknown quality, and therefore, unsafe for human consumption.

9.04 Shellfish Harvester Vessels

- A. All harvester vessel operators must ensure that any vessel used to harvest, handle, transfer and/or transport shellstock is properly constructed, operated and maintained to prevent contamination, deterioration and decomposition of the shellstock.
 - 1. Decks and containers shall be constructed and located as to prevent bilge water or polluted overboard water from coming into contact with the shellstock.
 - 2. Bilge pump discharges shall be located so that the discharge does not contaminate shellstock.
 - 3. Boat decks and storage bins used in the harvest, handling, transfer and/or transport of shellstock for direct market shall be:
 - (a) Kept clean with potable water or water from a growing area in the approved classification or in the open status of the conditionally approved classification; and
 - (b) Provided with effective drainage.
 - 4. Vessels and all other equipment coming into contact with shellstock during harvest, handling, transfer and/or transport shall be constructed in a manner and with materials that can be cleaned and maintained, repaired and/or replaced.
 - 5. When necessary, effective clean coverings shall be provided on harvest boats to protect against shellstock exposure to:
 - (a) Direct sunlight, birds; and
 - (b) Other adverse conditions.
 - 6. Cats, dogs and other animals shall not be allowed on the vessel except for patrol dogs when accompanying security or police officers.
- B. Disposal of Human Sewage From Vessels
 - 1. Human sewage shall not be discharged overboard from a vessel used in the harvesting of shellstock while the vessels are in the growing area.
 - 2. The Department shall educate all licensed harvesters and certified dealers concerning the public health significance of discharging human sewage overboard.
 - 3. An approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage.

DISCUSSION DOCUMENT ONLY
DOES NOT REPRESENT DEPARTMENT POLICY/REGULATION
DRAFT AS OF 07-11-2003

4. Portable toilets shall:
 - (a) Be used only for the purpose intended;
 - (b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage;
 - (c) Be emptied only into a sewage disposal system;
 - (d) Be cleaned before being returned to the boat; and
 - (e) Not be cleaned with equipment used for washing or processing food.
5. Use of other receptacles for sewage disposal may be approved by the Department if the receptacles are:
 - (a) Constructed of impervious, cleanable materials and have tight fitting lids; and
 - (b) Meet the requirements in Chapter 9.04(B)(4).

9.05 Vehicles Used to Transport Shellstock

- A. All vehicles used to transport shellstock shall be properly constructed, operated and maintained to prevent contamination, deterioration and decomposition of the shellstock.
- B. Storage bins on vehicles used in the transport of shellstock for direct marketing shall:
 1. Be kept clean with approved potable water or water from an approved area or conditionally approved area in the open status;
 2. Provide effective drainage; and
 3. Be covered to provide protection from contamination.
- C. Cats, dogs and other animals shall not be allowed in any part of the vehicle where shellstock are stored except for patrol dogs when accompanying security or police officers.

9.06 Shellstock Tagging and Labeling

- A. Each harvester licensed by the Department shall, prior to landing, securely affix a tag to each container he/she has harvested. If the harvest has occurred at more than one harvest location each container shall be tagged at the harvest location and must contain all information necessary to trace the shellfish back to the specific harvest area. Tags must be approved by the Department prior to use and be at least 2 ⁵/₈ inches x 5 ¹/₄ inches (6.7 x 13.3 cm) in size and be waterproof and durable.
- B. The harvester's tag (including bulk tags where approved for use by the Department) shall contain legible and indelible information arranged in the following order:
 1. Harvester's name;
 2. Harvester's Department license number;
 3. Date of harvest;

DISCUSSION DOCUMENT ONLY
DOES NOT REPRESENT DEPARTMENT POLICY/REGULATION
DRAFT AS OF 07-11-2003

4. Time of harvest, for the purpose of determining the time and temperature requirements in Chapter 9.08; and
5. The most precise identification of the harvest location, aquaculture lease site or LPA site as is practicable, including the initials of the state (Maine - ME), and the Department's designator of the growing area by indexing, administrative or geographic designation; e.g. flat or cove, river or bay, town, state. For example: White's Cove, Nonesuch River, Shellfishville, ME.
 - (a) Off shore vessels harvesting mahogany quahogs must provide identification as to the bay (if appropriate) and/or harvesting zones described by the Department.
6. The following statement, which must appear in bold capitalized type:
"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS".
7. The following consumer advisory statement from the Maine Food Code (01 Code of Maine Regulations, Chapter 331) regarding shellstock:
"RETAILERS, INFORM YOUR CUSTOMERS", and
"Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, poultry, or shellfish reduces the risk of food borne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information."
- C. In the instance where a certified dealer is also the harvester, the dealer's tag may also be used as the harvester's tag.
- D. It shall be unlawful for any person or persons other than the certified dealer to be in possession of unused certified dealer tags.
- E. The absence of tags as required by this regulation shall be prima facie evidence of a violation of these regulations and shall be grounds for the immediate embargo and/or destruction of the untagged shellstock as being of unsound or unknown quality, and therefore, unsafe for human consumption.
- F. Shellfish tags that do not contain the required information, or are altered or mislabeled, shall be grounds for the immediate embargo and/or destruction of the shellstock as being of unsound or unknown quality, and therefore, unsafe for human consumption.
- G. Example harvester tags are located at the end of this chapter.

DISCUSSION DOCUMENT ONLY
DOES NOT REPRESENT DEPARTMENT POLICY/REGULATION
DRAFT AS OF 07-11-2003

9.07 Shellfish Aquaculture

This section applies to persons who are issued an aquaculture lease pursuant to 12 M.R.S.A. §6072 or §6072-A, a limited-purpose aquaculture (LPA) license pursuant to 12 M.R.S.A. §6072-C, or is a registrant pursuant to Chapter 10.04(C) for quahogs or pursuant to Chapter 14.20 for European oyster.

The following graph summarizes the licensing, certification, record keeping and tagging requirements applicable to persons engaged in shellfish aquaculture in territorial waters.

A. Aquaculture permitting and licensing requirements

Activities	Additional license required	Certification (Chapters 15 & 16)	Record Keeping	Tagging
Nursery	None	No ¹	Yes ²	None
Personal Use Recreational Use No sale/barter/trade	None	No	Yes ³	None
Product raised for human consumption No processing Sold in State only	Harvester ⁴	No	Yes ⁵	Harvester ⁶
Product raised for human consumption Process, sell or ship to certified dealers, Inter- and Intra State Commerce	Wholesale Seafood ⁷	Yes ⁸	Yes ⁹	Dealer ¹⁰

¹ National Shellfish Sanitation Program, Model Ordinance (as of 04-18-03 throughout) Chapter VI (A-C)

² Model Ordinance Chapter VI.02(J), DMR Chapter 9.07(C) and Chapter 2.90(E)(4)

³ DMR Chapter 9.07(C) and Chapter 2.90(E)(4)

⁴ 12 MRSA §6601(2), Model Ordinance Chapter VI.02(B)(2)

⁵ DMR Chapter 9.07(C)

⁶ DMR Chapter 9.06

⁷ 12 MRSA §6851 and §6856

⁸ 12 MRSA §6851, §6856 and Model Ordinance

⁹ DMR Chapter 15.24

¹⁰ DMR Chapter 15.18-20, Model Ordinance Chapter VI.02(B)(3)

In accordance with Model Ordinance Chapter VI.01 Shellfish Aquaculture, a land based aquaculture facility operator/owner is exempt from being a dealer when nursery shellstock are 6 months or more growing time from market size.

DISCUSSION DOCUMENT ONLY
DOES NOT REPRESENT DEPARTMENT POLICY/REGULATION
DRAFT AS OF 07-11-2003

B. Marine Biotoxins

For any marine biotoxin-producing organism for which criteria have not been established under the National Shellfish Sanitation Program Model Ordinance, either cell counts in the water column or biotoxin meat concentrations may be used by the Department as the criteria for not allowing the harvest of shellstock.

- (a) Paralytic Shellfish Poisoning (PSP); Diarrhetic Shellfish Poisoning (DSP); Domoic Acid (ASP) and Neurotoxic Shellfish Poisoning (NSP)

When local sampling indicates PSP, DSP, ASP or NSP toxin is present in the area, or phytoplankton which may cause PSP, DSP, ASP or NSP toxin are found in the area, then analysis for PSP, DSP, ASP or NSP will be required prior to DMR approval for the harvest or sale of shellstock from the lease or LPA site. A minimum of twelve (12) shellfish must be submitted by the lease or LPA license holder to the DMR Public Health Division Biotoxin Laboratory, by contacting the Boothbay Harbor facility at (207) 633-9555 or the Lamoine facility at (207) 667-2418, at least five (5) business days prior to anticipated harvest.

Prior to approving the harvest or sale of shellfish from any lease or LPA site which has submitted shellfish samples to DMR, the DMR may, in its sole discretion, send samples to an accredited analytical laboratory for analysis for PSP, DSP, ASP or NSP toxin.

- (b) Requirements and procedures

Sample results will be reported to the lease or LPA license holder on a marine biotoxin analysis certificate issued by the DMR Public Health Division.

- (i) Monitoring

The cost of monitoring for marine biotoxins, when required under the provisions of this section, shall be paid for by the lease or LPA license holder. When monitoring is required, it must be done prior to the harvest of shellstock from the site for human consumption, or for any other commercial or non-commercial use.

(C) Closed Areas

Harvest of shellstock is prohibited in areas that are closed due to bacterial pollution pursuant to Chapter 95. For details about closure lines contact Marine Patrol Division I, west of Port Clyde, Tel. (207) 633-9595 or Marine Patrol Division II, east of Port Clyde, Tel. (207) 667-3373, or telephone the Shellfish Sanitation Hotline at 1-800-232-4733 or on the web at: <http://www.maine.gov/dmr/shellfish%20sanitation%20hot%20line.htm>. (Chapter 9.01(A))

(D) Record keeping

Complete, legible and accurate records of transport, transfer, harvest, and monitoring shall be maintained by the lease or LPA license-holder and must be made available for inspection for at least two (2) years. The records must include the:

- (1) Department's Lease ID or LPA license number, site location, date and data related to marine biotoxin analyses;
- (2) Source of shellfish, including seed if the seed is from growing areas which are not in the approved classification status pursuant to Chapter 2.90 and/or Chapter 15;
- (3) Dates of transplanting and harvest;

DISCUSSION DOCUMENT ONLY
DOES NOT REPRESENT DEPARTMENT POLICY/REGULATION
DRAFT AS OF 07-11-2003

- (4) Detailed records of sales;
 - (5) Water source, its treatment method, if necessary, and its quality in land based systems pursuant to Chapter 15.32, 15.33, 15.34 and or 15.35; and
 - (6) Records of the origin and health status of all seed or shellfish stocks reared on the lease or LPA site.
- (D) Shellfish harvested from the site must be kept in containers that prevent commingling of different harvest lots.

9.08 Shellstock Temperature Control

- A. Except as provided in Chapter 9.08(B), harvested shellstock shall be maintained in compliance with the following harvest time to temperature control requirements¹:

Table A.

ACTION LEVEL	AVERAGE MONTHLY MAXIMUM AIR TEMPERATURE	MAXIMUM HOURS FROM HARVEST TO TEMPERATURE CONTROL
LEVEL 1	<66 °F (18 °C)	36 hours
LEVEL 2	66 °F - 80 °F (19 °C - 27 °C)	24 hours
LEVEL 3	>80 °F (≥27°C)	20 hours

- B. If a growing area in the state has been confirmed as an original source of shellstock associated with two (2) or more incidents of *Vibrio parahaemolyticus* illness within the past three years, then the following harvest time to temperature controls in the time-temperature matrix below shall apply to shellstock from the affected growing area(s), which are intended to be consumed raw.

For the purposes of this control measure, growing areas in the State affected by *Vibrio parahaemolyticus* shall be identified and defined based on hydrographic and geographic parameters and other considerations relevant to control of a naturally occurring pathogen.

Table B.

ACTION LEVEL	AVERAGE MONTHLY MAXIMUM AIR TEMPERATURE	MAXIMUM HOURS FROM HARVEST TO TEMPERATURE CONTROL
LEVEL 1	<66 °F (18 °C)	36 hours
LEVEL 2	66 °F - 80 °F (19 °C - 27 °C)	12 hours
LEVEL 3	>80 °F (≥27°C)	10 hours

¹ The time and temperature control requirements are adopted to comply with the Model Ordinance, Chapter VIII Control of Shellfish Harvesting.

DISCUSSION DOCUMENT ONLY
DOES NOT REPRESENT DEPARTMENT POLICY/REGULATION
DRAFT AS OF 07-11-2003

9.09 Recall Procedure

- A. Complete, legible and accurate records of harvest and sales shall be maintained by the harvester and must be made available for inspection for at least one (1) year. The harvester transaction log template at the end of this chapter contains the required information for this purpose.
- B. Upon the determination that any shellstock or shellfish products harvested and/or sold by the harvester may have been contaminated with biotoxins, sewage, or any other poisonous or deleterious substances, or is otherwise of unsound or unknown quality, and therefore, unsafe for human consumption, the Department shall:
 - 1. Immediately notify the harvester that shellstock or shellfish products are being recalled;
 - 2. Specify the affected harvest area and date of harvest;
 - 3. Require the harvester to provide the following information to the Department, including any and all records regarding the same:
 - (a) The type and quantity of the shellstock or shellfish products harvested;
 - (b) The type and quantity shipped/sold and the name, address, phone number (if available) of the person shipped/sold to; and
 - (c) The quantity of all shellstock and shellfish products remaining in the possession of the harvester and all person(s) reported pursuant to Chapter 9.09(B)(3)(b) above. All products being held shall be considered embargoed.
 - 4. Advise all persons receiving the shellstock or shellfish products from the harvester that the products must not be further sold or shipped and that the products must be retained on the premises for inspection by Department official(s) or the Department's designated representative(s). All receiving and shipping records and invoices for the recalled shellfish or shellfish products must be made available to the Department at the time of the inspection.
- C. The Department official(s) or designated representative(s) shall inspect the shellstock or shellfish products subject to the recall, and shall review all receiving and shipping records and invoices relating to those shellstock or shellfish products. The Department may copy any or all of the receiving and shipping records and invoices and may, at its discretion take custody of the records and invoices for the purposes of inspection and copying. Shellstock or shellfish products which cannot be determined to be safe will be subject to immediate embargo and destruction as provided by 12 M.R.S.A. §6856(6).
- D. Harvesters who certify on their license that they will sell only to certified dealers shall be exempt from the recall record keeping requirements in Chapter 9.09 (this section).

DISCUSSION DOCUMENT ONLY
DOES NOT REPRESENT DEPARTMENT POLICY/REGULATION
DRAFT AS OF 07-11-2003

Harvester Name: _____

Harvester Address: _____

Harvester License Number: _____

SHELLSTOCK TRANSACTION LOG FOR HARVESTERS						
Harvest Date	Shellstock Type	Shellstock Quantity	Harvest Location	Date Sold	Quantity of Shellstock Sold	Sold To